

## Nuclear Regulatory Commission

## § 70.72

(2) A general description of the facility with emphasis on those areas that could affect safety, including an identification of the controlled area boundaries;

(3) A description of each process (defined as a single reasonably simple integrated unit operation within an overall production line) analyzed in the integrated safety analysis in sufficient detail to understand the theory of operation; and, for each process, the hazards that were identified in the integrated safety analysis pursuant to § 70.62(c)(1)(i)–(iii) and a general description of the types of accident sequences;

(4) Information that demonstrates the licensee's compliance with the performance requirements of § 70.61, including a description of the management measures; the requirements for criticality monitoring and alarms in § 70.24; and, if applicable, the requirements of § 70.64;

(5) A description of the team, qualifications, and the methods used to perform the integrated safety analysis;

(6) A list briefly describing each item relied on for safety which is identified pursuant to § 70.61(e) in sufficient detail to understand their functions in relation to the performance requirements of § 70.61;

(7) A description of the proposed quantitative standards used to assess the consequences to an individual from acute chemical exposure to licensed material or chemicals produced from licensed materials which are on-site, or expected to be on-site as described in § 70.61(b)(4) and (c)(4);

(8) A descriptive list that identifies all items relied on for safety that are the sole item preventing or mitigating an accident sequence that exceeds the performance requirements of § 70.61; and

(9) A description of the definitions of unlikely, highly unlikely, and credible as used in the evaluations in the integrated safety analysis.

### § 70.66 Additional requirements for approval of license application.

(a) An application for a license from an applicant subject to subpart H will be approved if the Commission determines that the applicant has complied

with the requirements of §§ 70.21, 70.22, 70.23, and 70.60 through 70.65.

(b) Submittals by existing licensees in accordance with § 70.62(c)(3)(i) will be approved if the Commission determines that:

(1) The integrated safety analysis approach is in accordance with the requirements of §§ 70.61, 70.62(c)(1), and 70.62(c)(2); and

(2) The schedule is in compliance with § 70.62(c)(3)(ii).

(c) Submittals by existing licensees in accordance with § 70.62(c)(3)(ii) will be approved if the Commission determines that:

(1) The requirements of § 70.65(b) are satisfied; and

(2) The performance requirements in § 70.61 (b), (c) and (d) are satisfied, based on the information in the ISA Summary, together with other information submitted to NRC or available to NRC at the licensee's site.

### § 70.72 Facility changes and change process.

(a) The licensee shall establish a configuration management system to evaluate, implement, and track each change to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel. This system must be documented in written procedures and must assure that the following are addressed prior to implementing any change:

(1) The technical basis for the change;

(2) Impact of the change on safety and health or control of licensed material;

(3) Modifications to existing operating procedures including any necessary training or retraining before operation;

(4) Authorization requirements for the change;

(5) For temporary changes, the approved duration (*e.g.*, expiration date) of the change; and

(6) The impacts or modifications to the integrated safety analysis, integrated safety analysis summary, or other safety program information, developed in accordance with § 70.62.